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09/800,689	03/07/2001	Penny Towne	98,541-K	5052

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EXAMINER

WALLENHORST, MAUREEN

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 07/22/2003

*Jo*

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/800,689

Applicant(s)

TOWNE ET AL.

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 USC 119(a)-(d), under 35 USC 119(e) and under 35 USC 120 as follows: The instant application does not name at least one common inventor with PCT/US99/20353, and therefore, priority to this application under 35 USC 119(a)-(d) cannot be claimed. The instant application also does not name at least one common inventor with provisional application no. 60/099,018, and therefore, priority to this provisional application under 35 USC 119(e) cannot be claimed. The instant application also does not name at least one common inventor with application serial nos. 09/721,096 and 09/259,240, and therefore, priority to these applications under 35 USC 120 cannot be claimed. The instant application is not a proper continuation of application serial no. 09/259,240, and is not a proper continuation-in-part of application serial no. 09/721,096. Therefore, US Patent no. 6,296,809 to Richards et al, which corresponds to application serial no. 09/259,240, qualifies as applicable prior art under 35 USC 102(e). See MPEP sections 201.07 and 201.08. It is noted that Applicants intend to file a change in inventorship under 37 CFR 1.48(a) in order to add additional inventors, thus obviating the problem of no common inventors between the instant application and the aforementioned applications upon which priority is desired to be based. However, no such change in inventorship has been received to date, and therefore, the previous rejections of the claims based upon the combination of Richards et al and Hartman et al is maintained.
2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

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The title of the invention in the declaration is different than the title of the invention on the first page of the specification.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being obvious over Richards et al (US Patent no. 6,296,809) in view of Hartman et al.

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Richards et al teach of a method and apparatus for automatically performing pathological staining and treating of tissue samples. Richards et al teach that it is important to treat the tissue samples analyzed therein so as to improve the accessibility of a stain to target molecules in cells (i.e. proteins, nucleic acids, lipids, etc.). Lack of accessibility is caused by the crosslinking of molecules and antigens in cells due to the fixation and preservation of the cells with aldehydes and other fixatives. Cross-linking of antigens causes a loss of antigenicity due to chemical modifications of antigenic proteins. Richards et al disclose that in order to improve the accessibility of a stain to a molecular target in a cell, the cells of a fixed tissue sample should undergo "cell conditioning". This is done by treating the cells with a composition, which comprises a citrate buffer as well as sodium dodecyl sulfate (SDS) and ethylene glycol. See lines 54-67 in column 15 and lines 1-16 in column 16 of Richards et al. The conditioning composition has a known molarity, pH and composition. It is noted that Richards et al is considered proper prior art against the instant claims since the effective filing date of the Richards et al patent is before the effective filing date of the instant application, and the instant application does not claim priority to the Richards et al patent. Richards et al fail to teach that the cell conditioning composition contains sodium metabisulfite therein.

Hartman et al teach of a tissue fixative composition that contains therein a bisulfite salt. The bisulfite salt can be a metabisulfite such as sodium metabisulfite. Hartman et al teach that this composition containing sodium metabisulfite serves to improve the morphology, antigen retention and antigenicity of tissue samples. See lines 15-40 in column 2 of Hartman et al.

Based upon a combination of Richards et al and Hartman et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to add sodium

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metabisulfite to the cell conditioning composition taught by Richards et al since Hartman et al teaches that sodium metabisulfite serves to improve the antigen retention and antigenicity of tissue samples, and the function of the cell conditioning composition taught by Richards et al is to improve the antigenicity of cells in tissue samples so that they may be more easily stained. It also would have been obvious to one of ordinary skill in the art to adjust the concentration levels of the components in the cell conditioning composition taught by Richards et al to the levels recited in the instant claims since concentration levels are easily determined and adjusted depending upon the user's particular preferences and the objective sought. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller et al*, 105 USPQ 233.

7. Applicant's arguments filed July 2, 2003 have been fully considered but they are not persuasive.

Applicants' attention is directed to paragraph no. 1 above for a discussion of Applicants' claim for priority and intention to file a change in inventorship under 37 CFR 1.48(a). The declaration is still objected to since a corrected declaration has not yet been received.

Applicants argue the rejection of the claims made under 35 USC 103 using the combination of Richards et al in view of Hartman et al by stating that the Patent Office has used hindsight reconstruction to formulate the rejection, and that there is no suggestion to combine these references, and no motivation within the references themselves to combine their teachings. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into

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account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the primary reference to Richards et al teaches of a cell conditioning composition containing therein a citrate buffer, sodium dodecyl sulfate (SDS) and ethylene glycol. Richards et al teach that this composition serves to improve the antigenicity of antigens on cells, which are cross-linked by aldehydes and other fixatives. The secondary reference to Hartman et al teaches that sodium metabisulfite serves to improve the morphology, antigen retention and antigenicity of tissue samples. See lines 15-40 in column 2 of Hartman et al. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to add sodium metabisulfite to the cell conditioning composition taught by Richards et al since Hartman et al teaches that sodium metabisulfite serves to improve the antigen retention and antigenicity of tissue samples, and the function of the cell conditioning composition taught by Richards et al is to improve the antigenicity of cells in tissue samples so that they may be more easily stained. Therefore, one of ordinary skill in the art would expect the addition of sodium metabisulfite to

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the cell conditioning composition taught by Richards et al to further improve the antigenicity of cells in tissue samples treated with a fixative in a synergistic manner.

Applicants argue that Richards et al only mentions SDS and ethylene glycol in a general manner, and that no specific concentrations or percentages are taught. In response to this argument, it is noted that the independent claims in the instant application also do not include specific concentrations or percentages for the components of the composition. In addition, the reference to Richards et al teaches that the cell conditioning compositions have “known molarity, pH and composition”. See lines 14-15 in column 16 of Richards et al. Therefore, in the absence of evidence to the contrary, one of ordinary skill in the art would be able to use routine experimentation to determine a known concentration or percentage level for each of the components in the composition taught by Richards et al ( i.e. the citrate buffer, the SDS and the ethylene glycol), in accordance with its intended use and function in the composition. If the composition taught by Richards et al has a known molarity, pH and composition, then the concentration levels for each component in the composition must be known and easily determined.

Applicants also argue that the secondary reference to Hartman et al only teaches of a fixative composition containing a bisulfite salt and an acidic buffer. Applicants argue that Hartman et al fail to teach of the inclusion of SDS or ethylene glycol in the fixative composition. In response to this argument, it is noted that the reference to Hartman et al is not used in the rejection under 35 USC 103 as the primary reference. The primary reference to Richards et al is used in the rejection to teach a base composition containing citrate buffer, SDS and ethylene glycol. Rather, Hartman et al is used as a secondary reference to teach the obviousness of adding



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sodium metabisulfite to the main composition taught by Richards et al since Hartman et al discloses the use of sodium metabisulfite to increase the antigenicity of cells in tissue samples.

For all of the above reasons, Applicant's arguments are not found persuasive.

8. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 703-308-3912. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Maureen M. Wallenhorst  
Primary Examiner  
Art Unit 1743

mmw

July 21, 2003

*Maureen M. Wallenhorst*  
**MAUREEN M. WALLENHORST**  
**PRIMARY EXAMINER**  
**GROUP 1800 1700**